DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

June 18, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2001-027

Ms. Monika Lekander, President
Salsbury Chemicals, Inc.
One Meadowland Plaza
East Rutherford, New Jersey 07073

Dear Ms. Lekander:

An inspection of [redacted] drug product manufacturing, NDA [redacted] at Salsbury Chemicals, Inc., 2002 Rockford Road, Charles City, Iowa by investigators of this office on April 9-13, 2001 disclosed significant deviations from Current Good Manufacturing Practice (CGMP) regulations set forth in Title 21 Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 & 211). These deviations cause the drug product to be adulterated within the meaning of Section 501(a)(2) (B) of the Federal Food, Drug, and Cosmetic Act (the Act).

CGMP deviations noted during the inspection included, but are not limited to:

The active pharmaceutical ingredient (API) for the covered product is not sampled for testing in a representative manner prior to use [21 CFR 211.84(b)].

Reliability of suppliers' analyses supporting drug component acceptance is not appropriately validated for all components [21 CFR 211.84(d)(2)].

Appropriate written procedures to prevent objectionable microbial contamination from environmental sources are not established and followed [21 CFR 211.113(a)].

The above noted violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure compliance with each requirement of the CGMP regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts. Additionally, NDA, ANDA or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and or injunction.

We have received and reviewed your firm's April 26 and June 1, 2001 written responses to inspectional findings. We recognize that some objectionable conditions had been corrected prior to the inspection, and some were corrected before the inspection was concluded. In addition, specific promises of correction were made in the written responses. However, the inspection covered process validation lots that were subsequently released for further processing to finished product by other firms. As such, postproduction corrections do not necessarily impact the significance of inspectional observations.

We cannot concur with your response concerning environmental monitoring. The response contains the statement that the drug sponsor and FDA's reviewing division had an understanding that there are no microbiological specifications or commitments in regard to your firm's operations. NDA Item 4.III.6, page 3 specifies the formulation room as class [redacted] and separations/solids room as class [redacted] Your response appears to imply that these room classifications only relate to baseline studies and not to day to day operating conditions. While there may be valid reasons that the industry standard of in-process environmental monitoring may not be feasible, data should be available to demonstrate that at a minimum, environmental conditions for each day of facilities use meet required specifications.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Noel G. Ferguson, Compliance Officer, Food and Drug Administration, 11630 West 80th St., Lenexa, Kansas 66214-3340.

Sincerely,

Mary Wolicke for
Charles W. Sedgwick
District Director
Kansas City District

Cc: Ms. Carol J. Leipzig
Regulatory Specialist, Q.A.
Salsbury Chemicals, Inc.
1205 Eleventh Street
Charles City, Iowa 50616

Mr. Russell C. Smith, Sr. Vice President
Operations and Site Manager
Salsbury Chemicals, Inc.
1205 Eleventh Street
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[redacted]